# EXHIBIT B

# Manual of PATENT EXAMINING PROCEDURE

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## 2117 Markush Claims [R-10.2019]

### I. MARKUSH CLAIM

A "Markush" claim recites a list of alternatively useable members. In re Harnisch, 631 F.2d 716, 719-20 (CCPA 1980); Ex parte Markush, 1925 Dec. Comm'r Pat. 126, 127 (1924). The listing of specified alternatives within a Markush claim is referred to as a Markush group or Markush grouping. Abbott Labs v. Baxter Pharmaceutical Products, Inc., 334 F.3d 1274, 1280-81, 67 USPQ2d 1191, 1196-97 (Fed. Cir. 2003) (citing to several sources that describe Markush groups). Claim language defined by a Markush grouping requires selection from a closed group "consisting of" the alternative members. Id. at 1280, 67 USPQ2d at 1196. See MPEP § 2111.03, subsection II, for a discussion of the term "consisting of" in the context of Markush groupings.

Treatment of claims reciting alternatives is not governed by the particular format used (e.g., alternatives may be set forth as "a material selected from the group consisting of A, B, and C" or "wherein the material is A, B, or C"). See, e.g., the Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications ("Supplementary Guidelines"), 76 Fed. Reg. 7162 (February 9, 2011). Claims that set forth a list of alternatives from which a selection is to be made are typically referred to as Markush claims, after the appellant in Ex parte Markush, 1925 Dec. Comm'r Pat. 126, 127 (1924). Although the term "Markush claim" is used throughout the MPEP, any claim that recites alternatively usable members, regardless of format, should be treated as a Markush claim. Inventions in metallurgy, refractories, ceramics, chemistry, pharmacology and biology are most frequently claimed under the Markush formula, but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. See, e.g., Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1297-98 (Fed. Cir. 2009)(claim to a hemodialysis apparatus required "at least one unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) dialysate-circulation unit. (iii) an ultrafiltrate-removal unit, and (iv) dialysate-monitoring unit" and a user/machine

interface operably connected thereto); In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980)(defining alternative moieties of a chemical compound with Markush groupings).

A Markush grouping is proper if the members of a group share a single structural similarity and a common use. See subsections II - IV, below, for guidelines regarding the determination of whether a Markush grouping is improper.

See MPEP § 2111.03 and MPEP § 2173.05(h) for discussions of when a Markush grouping may be indefinite under 35 U.S.C. 112(b) (e.g., if the list of alternatives is not a closed grouping, or if a Markush group is so expansive that persons skilled in the art cannot determine the metes and bounds of the claimed invention).

See MPEP § 803.02 for information pertaining to the election, search, and examination of claims that include at least one Markush grouping.

#### II. IMPROPER MARKUSH GROUPING

A Markush claim may be rejected under judicially approved "improper Markush grouping" principles when the claim contains an improper grouping of alternatively useable members. A Markush claim contains an "improper Markush grouping" if either: (1) the members of the Markush group do not share a "single structural similarity" or (2) the members do not share a common use. *Supplementary* Guidelines at 7166 (citing In re Harnisch, 631 F.2d 716, 721-22, 206 USPQ 300, 305 (CCPA 1980)).

Where a Markush grouping describes part of a combination or process, the members following "selected from the group consisting of" (or a similar introductory phrase) must be substitutable, one for the other, with the expectation that the same intended result would be achieved. Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1357 (Fed. Cir. 2016)("It is generally understood that ... the members of the Markush group ... are alternatively usable for the purposes of the invention ... .")(citations omitted). Where a Markush grouping describes part of a chemical compound, regardless of whether the claim is limited to a compound per se or the compound is recited as